AAH RSPP GUIDANCE
Reporting to AAHRP

PURPOSE
The purpose of this guidance is to provide direction to RSPP staff in reporting incidents to AAHRPP.

Definitions of Italicized words can be found in the AAH RSPP Glossary.

GUIDANCE
What incidents should be reported to AAHRPP?
The organization must report to AAHRPP any of the following incidents. The researcher is required to report these incidents to the RSPP office via a Significant New Information form (per the RSPP Guidance: Significant New Information)

1. Any negative actions by a government oversight office, including, but not limited to, OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated, FDA Restrictions Placed on IRBs or Investigators, and corresponding compliance actions taken under non-US authorities related to human research protections.
2. Any litigation, arbitration, or settlements initiated related to human research protections.
3. Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the Organization’s HRPP related to an incident of human subject research.

When should reporting occur?
As soon as possible but generally within 48 hours after the organization becomes aware.

REQUIREMENTS
• AAHRPP Accreditation Standards/Elements: I.5.D